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Inspections, Compliance, Enforcement, and Criminal Investigations

Fresh Express Incorporated 10/6/10



Department of Health and Human Services

Public Health Service
Food and Drug Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

Via UPS

October 6, 2010

Fernando Aguirre, President and CEO
Chiquita Brands International, Inc. and Fresh Express, Incorporated
250 East Fifth Street
Cincinnati, OR 45202

Dear Mr. Aguirre:

Starting on May 21, 2010 and ending on June 10, 2010, the Food and Drug Administration (FDA) inspected your food manufacturing facility located at 900 E. Blanco Road, Salinas, California. During this inspection, FDA investigators collected labels for your products and reviewed their labeling at

<http://www.chiquita.com>¹. Based on our review, we have concluded that your Chiquita brand "Pineapple Bites with Coconut" and "Pineapple Bites" products are misbranded in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and the applicable regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). You can find the Act and FDA regulations through links at FDA's Internet home page at <http://www.fda.gov>².

Specifically, your "Pineapple Bites with Coconut" product is misbranded within the meaning of Section 403(a) of the Act [21 U.S.C. § 343(a)] in that its statement of identity, "Pineapple Bites with Coconut", is false and misleading. The ingredient statement for this product states that it is made with coconut; however, our investigation determined that this product is made with a coconut flavor spray. The characterizing flavor of your Pineapple with Coconut product must be identified in accordance with 21 CFR 101.22(i)(1)(iii) (for example, "coconut flavor").

Your "Pineapple Bites" and "Pineapple Bites with Coconut" products are misbranded within the meaning of Section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because their labeling bears nutrient content claims but the products do not meet the requirements for the claims.

Specifically, their labeling includes the claim "Plus ... Antioxidants." However, this claim does not include the names of the nutrients that are the subject of the claim or, alternatively, link the term "antioxidants" by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity. 21 CFR 101.54(g)(4). Your use of this antioxidant claim therefore misbrands your products under section 403(r)(2)(A)(i) of the Act [21 U.S.C. § 343(r)(2)(A)(i)].

Your "Pineapple Bites" and "Pineapple Bites with Coconut" products also bear the claim "Plus Phytonutrients." "Phytonutrients" are not nutrients for which a recommended daily intake (RDI) or daily recommended value (DRV) has been established. Therefore, nutrient content claims regarding "phytonutrients" are not authorized and further misbrand your products under section 403(r)(2)(A)(i) of the Act [21 U.S.C. § 343(r)(2)(A)(i)]. To the extent phytonutrients are intended to be the basis for an antioxidant nutrient content claim, that use would violate FDA regulations for the same reason and because phytonutrients are not

recognized as having antioxidant activity. 21 CFR 101.54(g)(1) and (2).

Both your "Pineapple Bites" and "Pineapple Bites with Coconut" products also bear the statement "Only 40 Calories." This statement implies that the products are "low calorie" foods. A "low calorie" claim may be made if a food with a reference amount customarily consumed (RACC) greater than 30 grams (g) or greater than 2 tablespoons does not provide more than 40 calories per RACC. 21 CFR 101.60(b)(2)(i)(A). The RACC established for pineapple is 140 g. See 21 CFR 101.12(b) (Table 2, Fruits and Fruit Juices, All other fruits fresh, canned, or frozen).

The nutrition information for both products states that there are 40 calories per 1 piece (80 g) of product; this equals about 70 calories per RACC. Therefore, under 21 CFR 101.13(i)(2), the products are required to carry a disclaimer adjacent to the claim, e.g., "Only 40 calories per serving, not a low calorie food". Because your products fail to bear the required disclaimer, they are misbranded within the meaning of section 403(r)(1)(A) of the Act.

The "Pineapple Bites" and "Pineapple Bites with Coconut" products are further misbranded within the meaning of section 403(k) of the Act [21 U.S.C. 343(k)] in that they contain the chemical preservatives ascorbic acid and citric acid but their labels fail to declare these preservatives with a description of their functions. 21 CFR 101.22. Further, the ingredients ascorbic acid and citric acid must be declared by their common or usual names. 21 CFR 101.4(a).

This letter is not intended to be an all-inclusive review of your firm's products and processes. It is your responsibility to ensure that your firm and your products comply with the Act and FDA, regulations. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. For instance, we may take further action to seize your product or enjoin your firm from operating.

We also note that, FDA (through its contractor) obtained two samples of Fresh Express Hearts of Romaine, the testing of which yielded human pathogens. One sample was found to contain *Salmonella Anatum*; another sample was found to contain *E. coli* 0157:H7. We acknowledge that you issued letters to your customers in an effort to recall affected products. However, FDA recommends that you review your firm's criteria for receipt of raw product, your procedures for ensuring that wash, flume and processing water do not contaminate your products and any other conditions and practices that may relate to the cause of the contamination.

We further acknowledge your June 25, 2010 response to the Good Manufacturing Practices violations cited in the FDA Form 483 regarding this inspection. In your response, you committed to:

- Retrain employees to replace or sanitize their gloves after contacting unsanitized surfaces;
- Include the dryer hoist controls and the equipment control panels that involve direct employee contact in your daily wash and sanitation procedures;
- Create a new storage system for aprons, gloves, and sleeve guards for times during manufacturing when they are not in use; and
- Modify your cutting surface inspection and replacement program so that cutting surfaces will be changed after every **(b)(4)** of use.

However, you did not provide documentation to demonstrate that these corrections have been made. You also did not address the observation that your technician improperly read the free chlorine indicator tests in the flume water. Please provide this information and documentation in your response to this Warning Letter.

In addition to the labeling issues identified above, we note that the available labeling space is at least 6" in height; therefore, the size of the nutrition information declared on these packages is not appropriate and does not meet the formatting requirements under 21 CFR 101.9(d), including hairline and footnote requirements. We note that since some of the nutrients are at insignificant levels, a shortened version of the Nutrition Facts panel may be used, e.g., the statement "Not a significant source of dietary fiber", at the bottom of the table of nutrient values as allowed under 21 CFR 101.9(c).

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Please include documentation of the corrective actions you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to:

Darlene B. Almogela
Director of Compliance
United States Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502

If you have any questions about the content of this letter please contact Sergio Chavez, Compliance Officer, at 510-337-6886.

/s/

Barbara Cassens
District Director

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
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1. <http://www.chiquita.com/>
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